



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2014-0003]

RIN 0579-AD89

Importation of Apples from China

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the fruits and vegetables regulations to allow the importation of fresh apples (Malus pumila) from China into the continental United States. As a condition of entry, apples from areas in China in which the Oriental fruit fly (Bactrocera dorsalis) is not known to exist will have to be produced in accordance with a systems approach that includes requirements for registration of places of production and packinghouses, inspection for quarantine pests at set intervals by the national plant protection organization of China, bagging of fruit, safeguarding, labeling, and importation in commercial consignments. Apples from areas in China in which Oriental fruit fly is known to exist may be imported into the continental United States if, in addition to these requirements, the apples are treated with fumigation plus refrigeration. All apples from China will also be required to be accompanied by a phytosanitary

certificate with an additional declaration stating that all conditions for the importation of the apples have been met and that the consignment of apples has been inspected and found free of

quarantine pests. This action allows for the importation of apples from China into the continental United States while continuing to provide protection against the introduction of quarantine pests.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, RPM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2018.

SUPPLEMENTARY INFORMATION:

Background

The regulations in “Subpart—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–71, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

The national plant protection organization (NPPO) of China has requested that the Animal and Plant Health Inspection Service (APHIS) amend the regulations to allow apples (Malus pumila) from China to be imported into the continental United States.

In response to that request, we prepared a pest risk assessment (PRA) and a risk management document (RMD). Based on the conclusions of the PRA and the RMD, on July 18, 2014, we published in the Federal Register (79 FR 41930-41934, Docket No. APHIS-2014-0003) a proposal¹ to amend the regulations to authorize the importation of fresh apples into the continental United States, provided that the apples were produced in accordance with a systems approach consisting of the following requirements: Production by a grower who is part of a

¹ To view the proposed rule, its supporting documents, or the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0003>.

certification program administered by the NPPO of China; fruit bagging; pre-harvest NPPO inspection; packing in packinghouses that are registered with the NPPO; packinghouse procedures including traceback and box marking; post-harvest washing; waxing; treatment with inspection after packing for quarantine pests; issuance of a phytosanitary certificate; importation in commercial consignments only; sealed boxes; and location of apples in a cold storage facility while awaiting export to the continental United States. For apples from those areas of China south of the 33rd parallel, where the Oriental fruit fly (Bactrocera dorsalis) is known to exist, we proposed to require treatment in accordance with 7 CFR 305.2, which provides that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual, found online at http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.

We note that we are changing the bagging protocol from that which was set out in the proposed rule. The proposed systems approach would have required that bags remain on the fruit until its arrival at the packinghouse. In the final rule, we are requiring that the bags stay on until at least 14 days prior to harvest instead of remaining on the fruit until it reaches the packinghouse. Though we modeled the systems approach on a similar systems approach for the importation of pears from China, bag removal at this stage is a necessary practice among apple growers in countries where bagging protocols are employed as apples must be exposed to sunlight so that they may color up prior to harvest. Pears do not require similar treatment in order to achieve their coloration.

Bagging is an important mitigation; however, we believe that removing the bags for the last 14 days before harvest is unlikely to significantly increase the risk because bagging is only one mitigation out of a number that are part of a systems approach.

Apples produced south of the 33rd parallel will require an APHIS-approved treatment for Oriental fruit fly. Specifically, this is fumigation plus refrigeration. This treatment will effectively mitigate any pests that might be present on the fruit after the removal of the bags.

Most, if not all, of the apple production areas in China are north of the 33rd parallel. All of the Lepidoptera and Coleoptera listed in the PRA as following the pathway of fresh apples from China were assigned a medium risk of doing so. These pests are mitigated by a number of other factors apart from bagging, including commercial production only, culling at the packinghouse, and the required inspection by the NPPO of China.

APHIS does not expect this change to significantly increase the risk of pests from China apples. Growers will still be responsible for maintaining low pest populations of target quarantine pests, with oversight by the NPPO of China and APHIS. These measures and others, including removing fallen fruit, will maintain low pest populations in the production sites. The required culling will also remove pests from the pathway. The biometric sampling rate can be increased, if necessary, in order to look for pests that may be present in smaller numbers in consignments, thus heightening the level of phytosanitary security. In addition, the bags will be removed for 2 weeks in the fall, when temperatures are rapidly declining leading to winter and insects are prone to reduced activity leading to dormancy.

Some of the pests of concern primarily attack the fruit early in the season when the fruit is at a small stage. For example, the Rhynchites spp. adult weevils attack small, newly formed fruit in the spring and early summer and the eggs are laid in those fruit often causing fruit drop. The larvae develop in 3 or 4 weeks after the eggs are laid and the larvae emerge from the fruit and pupate in the soil. There is only one generation per year. Infested fruit are misshapen with feeding damage and can easily be identified and culled. These pests are very unlikely to be

present in the fruit in the fall when the bags are removed 2 weeks before the apples are harvested, and any infested, misshapen fruit would be unlikely to be packed and can be easily spotted upon inspection.

Some of the Lepidoptera species do not attack the fruit, and are only present on the fruit as contaminants, for example Cryptoblabes gnidiella primarily attacks fruit that has infestations of Homoptera sp., which produce honey dew. Small larvae feed on the honey dew and do not attack the fruit until they have grown to a larger stage. The larvae initially feed on the surface of the fruit and do not bore into the fruit. Based on the pest damage symptoms, inspection and culling will remove Lepidoptera pests from the pathway.

Carposina sasakii larvae may bore into the fruit near the calyx, but according to a 2014 data sheet from the European and Mediterranean Plant Protection Organization, “Infested apples exude a sticky gum, pears turn yellow and apricots ripen unevenly.”² These symptoms would allow any infested fruit to be readily detected during culling and inspections. The window for the pests to attack after the bags are removed is also very small; for approximately 90 percent of the time after blossom drop and fruit set, the fruit will be protected by bags.

The Euzophera spp. may also attack the bark of the trees as well as fruit. These pests build up in unmanaged and backyard fruit trees. Well-managed production sites will rarely have infestations.

² You may view the data sheet on the Internet at https://www.eppo.int/QUARANTINE/insects/Carposina_sasakii/CARSSA_ds.pdf.

Leucoptera malifoliella, the pear leaf blister moth, is a leaf mining species that is only found on the fruit if leaves are attached to the fruit. Leaves and other plant parts are prohibited, so the risk of importing this pest with the fruit is minimal. This pest is an external miner; any leaves or mines should be readily detected and culled or found during inspection.

The eight species of Tortricidae, (Adoxophyes orana, Archips micaceana, Argyrotaenia ljugiana, Cydia funebrana, Ulodemis trigrappa, Grapholita inopinata, Spilonota albicana, and Spilonota prognathana) are leaf rollers. They typically lay eggs on leaves and roll them up and feed on leaf tissue. When fruit are adjacent to leaves, the larvae may attack the fruit, usually leaving external feeding damage and sometimes boring into the fruit leaving visible holes and larval waste. These species are unlikely to be present in any numbers during the fall and are also expected to be controlled by required pest management and standard agricultural best practices. This, combined with the small amount of time that the fruit will be exposed when the bags are removed, will greatly reduce the possibility that these Tortricidae will follow the pathway. In addition APHIS readily inspects for Tortricidae on many commodities. The only time quarantine treatments are required is when high populations and frequent interceptions occur. APHIS does not expect this, but removal of production sites in any problem areas will allow APHIS to mitigate this risk further.

As noted previously, the window for pest attack after the bags are removed is very small (approximately 90 percent of the time after blossom drop and fruit set, the fruit will be protected by bags). Attacks on the fruit by Lepidoptera and Curculionidae pests during this time are unlikely when these pest populations are kept in check by good pest management and agricultural practices, which has been our experience with pears from China and we expect this to be true for apples. All of the Lepidoptera and Curculionidae pests are borers into the fruit

from eggs laid externally. Besides inspection for external oviposition, there will be larval holes and feeding damage and larval waste that is readily apparent on inspection. If necessary, APHIS can suspend production sites with pest interceptions until pest populations are mitigated.

We are also adding two post-harvest treatment requirements to those listed in the proposed rule. The RMD that accompanied the proposed rule required apples to undergo washing and waxing. This procedure was included because washing removes hitchhiking, casual, and surface pests associated with smooth-skinned fruit such as apples, and waxing also serves to eliminate many surface pests including Homoptera and mites. Washing and waxing may also remove external spores of plant pathogens.

The two treatments we are adding in this final rule are fruit brushing and spraying with compressed air. Fruit brushing will be required as an additional packinghouse treatment requirement, while spraying with compressed air will be an alternative to waxing. Brushing adds another level of phytosanitary protection against surface pests and external spores and spraying with compressed air serves the same purpose as waxing in removing hitchhiking, casual, and surface pests. While brushing and spraying with compressed air are not widely used in fruit processing in the United States, these treatments are commonly used in the fruit packing industry in China and other Asian countries. For example, in §319.56-65(c)(2), we require spraying with compressed air as a treatment for pineapples imported from Malaysia.

We solicited comments concerning our proposal for 60 days ending September 16, 2014. We received 128 comments by that date. They were from a national organization that represents U.S. apple producers, State departments of agriculture, a State representative, scientific advisory groups, an environmental organization, domestic apple producers, and private citizens. The comments that we received are discussed below, by topic.

General Comments on the Proposed Rule

One commenter asked what sort of outreach APHIS had conducted to publicize the availability of the proposed rule for comment. The commenter claimed that the number of comments received suggested that stakeholders and other interested parties were unaware of its existence.

We disagree with the commenter's assessment. As stated above, we received 128 comments on the proposed rule from a variety of commenters. In addition to notifying members of PPQ's Stakeholder Registry,³ we performed outreach activities to the following industry and trade groups: The U.S. Apple Export Council, the U.S. Apple Association, the Washington Apple Commission, the Northwest Horticultural Council, and the Apple Commodity Committee of Northwest Fruit Exporters.

A number of commenters stated that we produce sufficient apples domestically and should therefore not import apples from China.

Such prohibitions would be beyond the scope of APHIS' statutory authority under the Plant Protection Act (7 U.S.C. 7701 et seq., referred to below as the PPA). Under the PPA, APHIS may prohibit the importation of a fruit or vegetable into the United States only if we determine that the prohibition is necessary in order to prevent the introduction or dissemination of a plant pest or noxious weed within the United States.

³ You may sign up for the PPQ Stakeholder Registry on the Internet at <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new/>.

Additionally, as a signatory to the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), the United States has agreed that any prohibitions it places on the importation of fruits and vegetables will be based on scientific evidence related to phytosanitary measures and issues, and will not be maintained without sufficient scientific evidence. The blanket prohibitions requested by the commenters would not be in keeping with this agreement.

Another commenter suggested that we should instead focus on importing fruits and vegetables from Europe instead of China.

APHIS's phytosanitary evaluation process only begins once a country has submitted a formal request for market access for a particular commodity. APHIS does not solicit such requests, nor do we control which countries submit requests.

One commenter said that we should require that every imported apple be labeled as a product of China.

Under the Country of Origin Labeling (COOL) law, which is administered by the Agricultural Marketing Service, retailers, such as full-time grocery stores, supermarkets, and club warehouse stores, are required to notify their customers with information regarding the source of certain food, including fresh and frozen fruits. Any apples imported from China would be subject to such requirements.

Other commenters stated that, if imported Chinese apples were to be processed into products such as apple juice or applesauce, COOL would be circumvented.

While, as stated above, APHIS does not administer COOL and, as such, these concerns are outside the scope of our authority, we believe that the relatively high price of apples imported from China when compared to domestic apple prices will prevent a situation such as the one

described by the commenters. A full explanation of the economic factors associated with this rule, including apple pricing, see the section entitled, “Executive Order 12866 and Regulatory Flexibility Act.”

One commenter observed that the importation of apples from China would bypass U.S. regulations regarding plant origins, growing practices, and laborer and produce health standards set out by the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Labor (DOL).

While we agree that Chinese producers are not subject to DOL rules and regulations, given that DOL’s authority does not extend beyond the United States, we disagree with the assessment that apples from China would not be subject to agricultural standards. The regulations and the operational workplan set out requirements, including requirements regarding sourcing of apples only from registered places of production and growing practices which Chinese producers must meet in order to export apples to the United States. Further, the FDA samples and tests imported fruits and vegetables for pesticide residues. Yearly monitoring reports and information on the program may be found here:

<http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/UCM2006797.htm>.

A number of commenters were concerned about the environmental state of China, citing in particular, heavy metal pollution in the Chinese air, water, and soil as a specific concern. The commenters further suggested that potential Chinese use of pesticides currently banned in the United States would lead to contamination of crops shipped from that country.

While the United States does not have direct control over pesticides that are used on food commodities such as apples in other countries, there are regulations in the United States concerning the importation of food to ensure that commodities do not enter the United States

containing illegal pesticide residues. Through section 408 of the Federal Food, Drug, and Cosmetic Act, the EPA has the authority to establish, change, or cancel tolerances for food commodities. These EPA-set tolerances are the maximum levels of pesticide residues that have been determined, through comprehensive safety evaluations, to be safe for human consumption. Tolerances apply to both food commodities that are grown in the United States and food commodities that are grown in other countries and imported into the United States. The EPA tolerance levels are enforced once the commodity enters the United States. Chemicals such as DDT that are banned in the United States do not have tolerances on food commodities. Federal Government food inspectors are responsible for monitoring food commodities that enter the United States to confirm that tolerance levels are not exceeded and that residues of pesticide chemicals that are banned in the United States are not present on the commodities. Tolerance levels for all chemicals that are acceptable for use on apples may be found in EPA's regulations in 40 CFR 180.101 through 180.2020. Tolerance information can also be obtained at <http://www.epa.gov/pesticides/food/viewtols.htm>. Pesticide use in China is regulated by the Institute for the Control of Agrochemicals (ICAMA) under the current pesticide management law, the "Regulation on Pesticide Administration (RPA)". Under this authority, all pesticides are required to be registered and all pesticide handlers must be licensed. In addition, the ICAMA restricts or bans the use of any pesticide when evidence shows that the pesticide is an imminent hazard to crops, fish, livestock, the environment, or public health.

One commenter said that the FDA is currently unable to cope with its obligation to safety test the current level of imported food coming into U.S. markets. The commenter asserted that allowing the importation of apples from China would prove overly burdensome.

As stated previously, the FDA samples and tests imported fruits and vegetables for pesticide residues. We have received no indication from the FDA that they are unable to successfully carry out these duties. Furthermore, the commenter provided no support for the assertions regarding the FDA's oversight capabilities.

Comments on APHIS Oversight

Several commenters stated that there exists doubt that APHIS possesses the necessary resources to oversee and monitor the terms of the operational workplan and successfully intercept any quarantine pests as necessary. The commenters cited governmental budget cuts and staffing levels as the reason for these systemic weaknesses.

APHIS has reviewed its resources and believes it has adequate coverage across the United States to ensure compliance with its regulations, including the Chinese apple import program, as established by this rule. In addition, the APHIS International Services Area Director in Beijing serves as APHIS' representative in China in order to assess the operations of the program there.

Two commenters asked how APHIS will regulate apple shipments to avoid the importation of leaves and debris, which, the commenter stated, may pose a risk of introducing pests which may not feed or reproduce in or on the fruit.

APHIS inspectors have the authority to reject consignments that contain contaminants such as leaves and other plant debris, especially if any pests are found to be generally infesting that shipment. As stipulated in § 319.56-3(a), "All fruits and vegetables imported under this subpart, whether in commercial or noncommercial consignments, must be free from plant litter or debris and free of any portions of plants that are specifically prohibited in the regulations in this subpart."

One commenter stated that APHIS would be unable to directly participate in the Chinese import program until such time as a pest infestation or other problem arose. The commenter suggested that APHIS expand its oversight to allow for action prior to that point.

Contrary to the commenter's assertion, our standard practice is to conduct site visits prior to the initiation of any import program. This is to ensure that all required mitigations are in place and the agreed upon operational workplan is being enforced. Subject matter experts inspect production sites and packinghouses and report their findings to APHIS. Furthermore, the operational workplan authorizes the APHIS International Services Area Director in Beijing to conduct periodic audit visits of production sites.

Comments on Chinese Oversight

A number of commenters expressed distrust in the Chinese NPPO's ability to maintain the program at an acceptable level of compliance. One commenter specifically cited an FDA report that highlights risks associated with China's inadequate enforcement of food safety standards. Another commenter stated that contaminants such as arsenic are of concern, citing a paper entitled "Current Research Problems of Chronic Arsenicosis in China"⁴ (June 2006).

Like the United States, China is a signatory to the SPS Agreement. As such, it has agreed to respect the phytosanitary measures the United States imposes on the importation of plants and plant products from China when the United States demonstrates the need to impose these measures in order to protect plant health within the United States. The PRA that accompanied the proposed rule provided evidence of such a need. That being said, as we mentioned in the proposed rule, APHIS will monitor and audit China's implementation of the systems approach for the importation of apples into the continental United States. If we determine that the systems

⁴ You may view the paper on the Internet at <http://bioline.org.br/pdf?hn06022>.

approach has not been fully implemented or maintained, we will take appropriate remedial action to ensure that the importation of apples from China does not result in the dissemination of plant pests within the United States.

The report referenced by the commenter was prepared by the United States Department of Agriculture's (USDA) Economic Research Service⁵ utilizing data collected by the FDA. The report found that three broad categories of products—fish and shellfish, fruit products, and vegetable products—combined accounted for 70 to 80 percent of FDA import refusals from China in recent years. Fruit and vegetable products are those that have been processed in China before being shipped to the United States, whereas the main concern when it comes to contamination of unprocessed fruits and vegetables is the presence of plant pests being introduced into the United States via the importation of unprocessed fruits and vegetables. Given the findings of the PRA, we are confident that the systems approach required for apples from China will mitigate the risk posed by such apples to introduce these pests. The other paper cited by the other commenter refers only to the effects of arsenic in drinking water and not to food contamination. As stated previously, FDA samples and tests imported fruits and vegetables for pesticide residues as well as other adulterants and additives, such as arsenic.

Several commenters expressed concern that the rule gives authority for inspecting for pests to the NPPO of China and therefore U.S. phytosanitary security would be under the purview of a foreign government.

While it is true that after initial APHIS approval of the export program is made, the required regular inspections are the responsibility of the NPPO of China, APHIS may request

⁵ The report, entitled, "Imports From China and Food Safety Issues," (July 2009) may be viewed on the Internet at http://www.ers.usda.gov/media/156008/eib52_1_.pdf.

submission of inspection records at any time. In addition, port of entry inspection is performed by trained agriculture specialists employed by U.S. Customs and Border Protection (CBP).

A commenter pointed out that we had modeled the systems approach on a similar systems approach for the importation of pears from China, and that pears imported under this protocol had sometimes been determined to be infested with plant pests. The commenter stated that this calls into question the efficacy of China's ability to employ the systems approach.

The pest interceptions referred to by the commenter were 15 infested pears over a 15 year period. Given the lengthy time period in question and the level of imports during that time, this interception rate does not call into question the efficacy of the systems approach, but rather underscores its quality.

One commenter stated that Chinese producers are not subject to the same regulatory oversight as U.S. producers and therefore would be at a competitive advantage. The commenter said that the United States should not accept any produce or products from China for that reason.

As stated previously, such a prohibition would be beyond the scope of APHIS' statutory authority under the PPA, whereby APHIS may prohibit the importation of a fruit or vegetable into the United States only if we determine that the prohibition is necessary in order to prevent the introduction or dissemination of a plant pest or noxious weed within the United States. Additionally, as a signatory to the World Trade Organization's SPS Agreement, the United States has agreed that any prohibitions it places on the importation of fruits and vegetables will be based on scientific evidence related to phytosanitary measures and issues, and will not be maintained without sufficient scientific evidence. The blanket prohibition requested by the commenters would not be in keeping with this agreement.

One commenter said that, apart from the requirements specifically listed in the regulations and the operational workplan, the methods of growth, harvest, treatment, and export of apples from China are generally unknown. The commenter argued that this makes it difficult for APHIS to ensure that the apples were handled with care, without pesticides banned in the United States, and with the precautions necessary to prevent the introduction of invasive pests. The commenter concluded that, until a more strictly monitored set of requirements are established, APHIS should not allow the importation of apples from China.

We disagree with the commenter's assessment. The commenter is asking for certain requirements that either the mandatory systems approach does require or does not need to address for reasons we have explained above. Further, the commenter's characterization of the extent of the operational workplan is incorrect. While the regulations themselves are written more broadly to allow for programmatic flexibility, operational workplans establish detailed procedures and guidance for the day-to-day operations of specific import/export programs. Workplans also establish how specific phytosanitary issues are dealt with in the exporting country and make clear who is responsible for dealing with those issues.

The NPPO of China is expected to maintain program records for at least 1 year and provide them to APHIS upon request. One commenter asked why we only expect the NPPO of China to maintain program records for 1 year. The commenter suggested that we make record maintenance a permanent requirement.

There is no technical justification for keeping records for longer than 1 year. If a pest problem is detected, the immediate past records will likely offer the most valuable information necessary to aid in resolution of the issue. This period of time is the APHIS standard for almost all pest programs and there is no special justification to extend it here.

General Comments on Phytosanitary Security

A commenter expressed concern that apples from China pose a high risk of introducing quarantine pests into the United States. Another commenter asked that APHIS prove that any pests associated with the importation of apples from China would lend themselves to effective control measures if they were to become established in the United States. Another commenter asked if APHIS has experience with the listed pathogens to ensure that the proposed mitigations will be effective in controlling diseases that are not present in the United States. Another commenter said that the RMD's report of 15 pest interceptions in 15 years in the Chinese pear importation program, which features a similar pest complex and mitigation measures as were proposed for Chinese apples, calls the efficacy of the systems approach into question. The commenter concludes that interception records cover only known interceptions and ignores the possibility of infested or diseased fruit that is imported but not detected.

For the reasons explained in the proposed rule, the RMD, and this final rule, we consider the provisions of this final rule adequate to mitigate the risk associated with the importation of apples from China. The commenters did not provide any evidence suggesting that the mitigations are individually or collectively ineffective.

One commenter suggested that past history bears out the fact that invasive species from China may prove to be destructive plant pests. The commenter cited the brown marmorated stink bug, Halyomorpha halys, and the vinegar fly, Drosophila suzukii, as two examples that are causing significant damage to American crops.

As stated above, we consider the provisions of this final rule adequate to mitigate against the pests of concern as identified by the PRA. Specific to the commenter's examples, both pests have been present in the United States for many years and originated in Asia, not necessarily

China in particular. The brown marmorated stink bug most likely entered the United States as a hitchhiking insect overwintering in a cargo container. Drosophila suzukii possibly made its initial entrance via importation of strawberries. Strawberries have been permitted entry from almost all countries since well before APHIS began requiring PRAs. Neither of these pests has been identified as being associated with a crop that has been permitted importation into the United States subsequent to the preparation of a PRA. Rather they are hazards of international trade, which occur infrequently over the span of decades.

Another commenter stated that APHIS lacks information on the full range of pests associated with apples imported from China as Chinese literature sources have proven deficient or incomplete.

We disagree. The PRA that accompanied the proposed rule provided a list of all pests of apples known to exist in China. This list was prepared using multiple data sources to ensure its completeness. For this same reason, we are confident it is accurate. Further, the pest complex associated with apples from China is very similar to the pest complex associated with pears from China, which have been imported into the United States for 15 years under a very similar systems approach with very few pest interceptions.

Another commenter observed that certain areas in the United States must establish buffer zones to keep non-commercially grown apples separated from high production orchards in order to maintain pest freedom. The commenter stated that phytosanitary treatments or other measures, such as those we proposed to require for apples from China, were insufficient to achieve this separation domestically and therefore a similar quarantine is necessary in China.

APHIS will require bagging and phytosanitary treatment to mitigate risk of fruit flies and other insects in apples imported from China. The bagging is an equivalent measure to a domestic quarantine since, done correctly, bagging excludes pest species from the fruits. We are also requiring additional mitigation measures including fumigation plus refrigeration for those apples grown in areas where the Oriental fruit fly is known to exist. In the United States, bagging is not used as a mitigation measure for fruit because of the labor requirements necessary to bag each fruit. Bagging is used as a mitigation for fruit from China, Japan, and Korea, because it is a culturally indigenous mitigation to those countries and because large scale labor at a lower cost is available to apply the mitigation.

One commenter stated that while the RMD asserts that the designated phytosanitary measures will mitigate the risk presented by the importation of apples from China into the continental United States, the document makes no claim as to a specific amount of risk reduction. The commenter further states that the RMD does not establish an appropriate level of phytosanitary protection, or state that the listed mitigation measures will achieve such a level. The commenter said that the PRA should provide more precise and preferably quantitative information about the likelihood that imported apple fruit would transmit any actionable pest or disease. The commenter concluded that APHIS has never established or published any explicit level, either qualitative or quantitative, by which it consistently judges risk.

APHIS believes that a qualitative analysis is appropriate in this situation. APHIS' evaluations are based on science and conducted according to the factors identified in § 319.5(d), which include biosecurity measures, projected export quantity, and the proposed end use of the imported commodity (e.g., propagation, consumption, milling, decorative, processing, etc.). Most of APHIS' risk assessments have been, and continue to be, qualitative in nature. Contrary

to the commenter's assertion that a qualitative analysis should include an explicit level of phytosanitary protection, the relative flexibility afforded by a qualitative analysis allows us to evaluate commodity import programs in a holistic way.

While APHIS believes that quantitative risk assessment models are useful in some rare cases, qualitative risk assessments, when coupled with site visit evaluations, provide the necessary information to assess the risk of pest introduction through importation of commodities such as apples from China. Additionally, there are several disadvantages associated with the use of quantitative risk assessment models. Quantitative models also tend to be data-intensive, and the types of data required by such models are often not available or adequate. Quantitative models are also necessarily developed using a set of assumptions that may not always adequately represent the biological situation in question, thus resulting in a wide range of uncertainty in interpretation of the model outcomes. The models also require constant updating, which is dependent on availability of current research and data, and thus may not always represent the current state of scientific information. Finally, uncertainty in the results or outcomes of quantitative models also arises from a large number of sources, including problem specification, conceptual or computational model construction and model misspecification, estimation of input values, and other model misspecification issues. Neither the regulations in 7 CFR part 319 nor APHIS guidance documents require a quantitative risk analysis or indicate that one is needed here.

The same commenter said that the PRA's assessment that certain of the pests considered were "unlikely" or "highly unlikely" to follow the pathway of importation of apples from China was not the same thing as stating that these pests would never follow the pathway. The commenter went on to say that the PRA provides no quantitative indication of what level of incidence is signified by the determinations "unlikely" and "highly unlikely." The commenter added that the systems approach specified in the proposed rule could prove ineffective if one of the pests deemed "unlikely" or "highly unlikely" to follow the pathway were imported, as the elements of the systems approach were not developed with those pests in mind.

For the reasons stated previously, APHIS rarely performs quantitative risk assessments. However, just because the risk is not quantified does not mean it cannot be assessed and mitigated. Each organism carries its own risk of following the pathway, and APHIS has been very successful in assessing and mitigating the risks associated with new market access. We have stated in the past that if zero tolerance for pest risk were the standard applied to international trade in agricultural commodities, it is quite likely that no country would ever be able to export a fresh agricultural commodity to any other country. Our pest risk analysis process will identify and assign appropriate and effective mitigations for any identified pest risks. If, based on our PRA, we conclude that the available mitigation measures against identified pest risks are insufficient to provide an appropriate level of protection, then we will not authorize the importation of the particular commodity.

The same commenter claimed that the brevity of the RMD, particularly the portion evaluating the efficacy of the proposed mitigation measures, was of concern given the biologic and economic complexities of the proposed action.

It would be inappropriate for APHIS to include an economic analysis in the RMD. Our economic assessment of this action may be found in both the initial regulatory flexibility analysis that was made available with our July 2014 proposed rule and the final regulatory flexibility analysis prepared for this final rule. Copies of the full analyses are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We disagree with the commenter's claim that the length of a document is in any way directly correlated to the efficacy of the mitigation measures discussed therein. The bagging requirements for all fruit intended for export will exclude almost all pests. We are confident of this fact because similar pest mitigations have successfully been used to allow for the importation of pears from China, which have a similar pest complex to apples from China. The pear importation program has been highly effective—15 pest interceptions in 15 years—with an import volume of about 10,000 metric tons (MT) annually. Although the bagging requirement differs slightly from that used for pears, we have detailed previously why the phytosanitary protections are expected to be effective.

The same commenter stated that the low interception rate reported in the RMD does not prove the efficacy of the proposed mitigation measures. The commenter argued that interception rates of fruit with a high actual infestation rate may be low or even zero if the inspection procedure has a low sensitivity or sampling rate. The commenter concluded that, because the RMD includes no information about inspection sensitivity or sampling rate, there is not enough information available to determine if the low interception rate truly reflects reality or if it is instead due to low inspection sensitivity or sampling.

Generally, CBP inspectors use a sample rate of 2 percent as a standard sample rate. Specific sampling rates may be adjusted based on various factors including the inspector's experience working with the shipper and the type of fruits or vegetables being imported. The standard sample rate may be increased for smaller shipments, or for a shipper or commodity that the inspector is encountering for the first time. APHIS reserves the right to suspend a program and readjust sampling levels accordingly if unacceptable levels of pests are detected.

The RMD included a description of packinghouse culling, which is a standard industry practice to remove all obviously blemished, diseased, and insect-infested fruits from the importation pathway. The same commenter argued that the RMD's supposition of the efficacy of culling ignores the potential existence of diseased, and insect-infested fruit that are not obviously diseased or insect-infested. The commenter said that, in the projected 10,000 MT of apples imported from China, the likelihood of a number of asymptomatic diseased or insect-infested fruit may not be negligible.

We are confident that packinghouse culling, in concert with the other requirements of the systems approach will be effective in mitigating phytosanitary risk. Any fruit that appeared asymptomatic, as posited by the commenter, would likely be in the early stages of disease or infestation. Given the transit time required to ship apples from China to the United States as well as mandatory port of entry inspections, it is likely that any latent infection or infestation would be detected at this point in the importation process. We have stated in the past that if zero tolerance for pest risk were the standard applied to international trade in agricultural commodities, it is quite likely that no country would ever be able to export a fresh agricultural commodity to any other country and, thus, zero risk is not a realistic standard.

The same commenter cited Article 5.4 of the SPS Agreement, which requires that members institute phytosanitary requirements while simultaneously minimizing negative trade effects; and Article 5.6, which requires that members ensure that any required phytosanitary measures are not more trade-restrictive than necessary, taking into account technical and economic feasibility. The commenter noted that the RMD contains no analysis indicating that the proposal is compliant with these articles and goes on to state that the RMD only evaluates one option, which consists of 14 specific measures. The commenter suggested that, if evaluated individually and in varying combinations, fewer than the 14 measures presented might prove sufficient to mitigate the phytosanitary risk posed by apples from China, a smaller systems approach that would be easier to implement and less trade-restrictive.

APHIS has determined that the listed risk management measures, along with the requirement of a phytosanitary certificate and the port of entry inspection, will mitigate the risk of pest introductions on apples from China into the continental United States. While bagging is the primary mitigation, the other mitigations serve to ensure that no pests will follow the importation pathway. Once the system has been in place and is operational, it may become clear that some mitigations may be reduced or removed. Prior to the program becoming operational, APHIS will not remove mitigations since, as stated previously, a similar systems approach is successfully utilized for the importation of pears from China. Although the bagging requirement differs slightly from that used for pears, we have detailed previously why the phytosanitary protections otherwise remain the same.

The commenter went on to state that the RMD provides no evidence to support the assertion that the 14 phytosanitary measures are sufficient to mitigate the pest risk associated with the importation of apples from China. In particular, the commenter observes that there is no description of apple growing or commercial apple processing in China that would support the claim that standard packinghouse procedures, such as culling and inspection, will prove efficacious. Similarly, another commenter stated that the required inspections do not guarantee that quarantine pests will not be introduced.

APHIS (and its predecessor agencies within the USDA) has been relying on inspection for almost 100 years to remove pests and we are therefore confident in its efficacy as a mitigation. As stated previously, APHIS' evaluations are based on science and conducted according to the factors identified in § 319.5(d). Specifically, paragraph (d)(5) of that section requires that any country requesting market access for a specific commodity to submit a full account of measures currently utilized in-country to mitigate against pests of concern in a domestic setting. We also require references to back up the information supplied by the country. APHIS then conducts its own assessment of the in-country mitigations, which includes multiple site visits in order to assess potential places of production, packinghouses, etc. We are confident that we have fully taken into account the ability of Chinese producers and the NPPO of China to meet the standards set out in the systems approach and the operational workplan.

The same commenter stated that Article 6.3 of the SPS Agreement requires that, “Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively.” The

commenter said that APHIS does not provide any information about evidence provided by China concerning pest- or disease-free areas or areas of low pest or disease prevalence within China or within specific regions in China. The commenter concluded that it appears that APHIS never even considered the existence of pest- or disease-free areas or areas of low pest or disease prevalence.

While the section of the SPS Agreement cited by the commenter is accurate concerning official recognition of pest- or disease-free areas or areas of low pest or disease prevalence, the recognition of such areas requires a formal request be made on the part of the exporting country. China did not request that APHIS recognize any such areas. Consequently, APHIS is not establishing formal pest- or disease-free areas or areas of low pest or disease prevalence in relation to the importation of apples from China, nor are such designations a requirement for the importation of commodities into the United States. As stated previously, we are confident that the systems approach provides the necessary pest mitigation for the importation of apples into the continental United States.

The same commenter said that the PRA's lack of information concerning pest and disease prevalence in China calls into question the adequacy of China's pest and disease surveillance programs and added that the PRA does not provide the information necessary for a determination regarding the adequacy of pest and disease surveillance. The commenter stated that there may be pests and diseases of concern not considered by the PRA and RMD due to the potential inadequacy of Chinese phytosanitary surveillance.

As stated previously, APHIS' evaluations are based on science and conducted according to the factors identified in § 319.5(d). Specifically, the requirements of paragraphs (d)(4) and (d)(5) of that section require that any country requesting market access for a specific commodity

must submit to APHIS a complete list of pests present in that country that are associated with the commodity in question as well as the measures currently utilized in-country to mitigate against those pests in a domestic setting. We also require references to back up the information supplied by the country. APHIS then conducts its own assessment of the pest complex and in-country mitigations, which includes multiple site visits in order to assess potential places of production, packinghouses, etc.

Another commenter asked if APHIS will require a trapping program be established for the listed pests of concern.

As stated in the proposed rule, paragraph (b)(1) would require the place of production to carry out any phytosanitary measures specified for the place of production under the operational workplan. Depending on the location, size, and plant pest history of the orchard, these measures may include surveying protocols or application of pesticides and fungicides. Trapping programs may be required in the case of fruit fly, key Lepidoptera, and/or weevils. This will be decided on a case-by-case basis, with the details of any such programs laid out in the operational workplan.

Comments on the Pest List

The PRA that accompanied the proposed rule identified 21 pests of quarantine significance present in China that could be introduced into the continental United States through the importation of Chinese apples:

- Adoxophyes orana (Fischer von Röslerstamm), summer fruit tortrix.
- Archips micaceana (Walker), a moth.
- Argyrotaenia ljugiana (Thunberg), grape tortrix.
- Bactrocera dorsalis (Hendel), Oriental fruit fly.
- Carposina sasakii Matsumura, peach fruit moth.

- Cenopalpus pulcher (Canestrini & Fanzago), flat scarlet mite.
- Cryptoblabes gnidiella (Millière), honeydew moth.
- Cydia funebrana (Treitschke), plum fruit moth.
- Euzophera bigella (Zeller), quince moth.
- Euzophera pyriella Yang, a moth.
- Grapholita inopinata Heinrich, Manchurian fruit moth.
- Leucoptera malifoliella (Costa), apple leaf miner.
- Monilia polystroma van Leeuwen, Asian brown rot.
- Monilinia fructigena Honey, brown fruit rot.
- Rhynchites auratus (Scopoli), apricot weevil.
- Rhynchites bacchus (L.), peach weevil.
- Rhynchites giganteus Krynický, a weevil.
- Rhynchites heros Roelofs, a weevil.
- Spilonota albicana (Motschulsky), white fruit moth.
- Spilonota prognathana Snellen, a moth.
- Ulodemis trigrapha Meyrick, a moth.

We received a number of comments regarding these pests as well as suggestions for other pests commenters believed to be of phytosanitary significance that were not included.

One commenter stated that many irrelevant species, such as longhorn beetles (Cerambycidae sp.), were included in the PRA. The commenter said that the PRA should focus only on those pests associated with apple fruit or those that could be transported with the

commodity. The commenter said that including a number of species that do not meet those criteria results in a large document, which renders it difficult to assess pests that may be of true significance and thus determine the quality and value of the PRA.

Our task in developing the PRA was to review all pests of apple that are present in China and then assess how likely they are to be associated with harvested fruit. For the sake of transparency, we include those pests that we conclude are not of quarantine significance or unlikely to follow the pathway of importation as we must first identify all pests that exist in China before narrowing the list to the specific pests of concern. This allows stakeholders and other interested parties the fullest degree of access to the pest list.

Another commenter wanted to know whether the reference to “stem” as the plant part affected in the PRA includes the fruit pedicel, which may, in some cases, be attached to the fruit in the marketplace. The commenter said that if the term “stem” refers only to woody tissue, such as an apple branch, then the commenter agrees with many of the assessments made regarding infestation of stems and the likelihood of such a pest following the pathway of importation. The commenter went on to state that many of the pests in the Cerambycidae, Lucanidae, Scolytinae, Tenebrionidae, and Curculionidae species listed in the PRA may infest stems and also the fruit pedicel, which would mean they could potentially pose a phytosanitary risk.

We considered the importation of apple fruit only, with no stem attached. This does not include the fruit pedicel.

Another commenter observed that the PRA did not consider the risks posed by those pests of phytosanitary concern in the United States that may be present in China but are not currently reported or known to be present. The commenter additionally stated that the PRA did not consider the risks posed by those pests that are of phytosanitary concern in the United States that are present in China but not currently reported to be associated with apples.

A second commenter stated that one of the general challenges encountered in reviewing the PRA is in understanding the biology of some of the exotic insect species and the specific risk of early season latent infection or late season infestation that may not be unequivocally obvious at harvest.

We believe that the standard suggested by the commenters would call for APHIS to postulate based on wholly unknowable risk factors. The PRA that accompanied the proposed rule provided a list of all pests of apples known to exist in China. This list was prepared using multiple data sources to ensure its completeness. For this same reason, we are confident it is accurate.

If, however, a new pest of apples is detected in China, APHIS will conduct further risk analysis in order to evaluate the pest to determine whether it is a quarantine pest, and whether it is likely to follow the pathway of apples from China that are imported into the United States. If we determine that the pest is a quarantine pest and is likely to follow the pathway, we will work with the NPPO of China to adjust the pest list and related phytosanitary measures to prevent its introduction into the United States.

Since the Oriental fruit fly is known to exist, in varying population densities, in areas of China south of the 33rd parallel, apples from such areas will be subject to treatment in accordance with 7 CFR part 305. Within part 305, § 305.2 provides that approved treatment

schedules are set out in the PPQ Treatment Manual, found online at http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf. (The manual specifies that fumigation plus refrigeration schedule T108-a is effective in neutralizing Oriental fruit fly on apples.) The RMD also states that any other treatment subsequently approved by APHIS may be used. One commenter expressed concern at the non-specific nature of those potential alternative treatments.

While APHIS cannot offer specifics on phytosanitary treatments that are not currently approved for use, the language in the RMD is intended to indicate that such treatments may become available in the future. APHIS has a rigorous procedure for approving new quarantine treatments, which includes soliciting comments from stakeholders in accordance with § 305.3. New treatments are tested to a very high standard of efficacy. Generally speaking, that means that an approved treatment is effective in removing 99.99 percent of pests.

Another commenter said that there is a lack of research to support that the systems approach proposed by APHIS will be effective in mitigating the phytosanitary risk posed by the Oriental fruit fly.

We disagree with the commenter's assertion. These mitigations have been used on a similar pest complex for the importation of pears from China. This is a highly successful import program with only 15 interceptions of any quarantine pests in 15 years of operation and no fruit fly interceptions. As most apples in China are grown above the 33rd parallel, the risk of fruit fly interceptions in consignments of apples is small. The commenter provided no specific data to support the argument that apples from China pose a unique pest risk.

One commenter stated that the Oriental fruit fly and the apple leaf miner are of particular concern given that they are high risk pests and Oriental fruit flies have been detected on numerous occasions at U.S. ports of entry.

While it is true that APHIS has made interceptions of Oriental fruit fly at U.S. ports of entry, most of those interceptions were in passenger baggage. Oriental fruit fly is additionally present in Hawaii, which may lead to a higher number of interstate interceptions.

Another commenter said that melon fly (Bactrocera cucurbitae) and solanum fruit fly (Bactrocera latifrons) are known pests of apple, but the PRA states that non-cucurbit hosts require confirmation. The commenter reasons that, for such severe pests of commodities other than apple, it would make sense to consider both as potential pests of apple. The commenter asked if there are areas of overlap between the flies' distribution areas and apple growing areas. Lastly, the commenter said that the honeydew moth (Cryptoblabes gnidiella) remained on the list in spite of the facts that the pest has a warm climate distribution and that apple is only an occasional host. The commenter said it would therefore be consistent to treat melon fly and solanum fruit fly similarly.

These particular fruit flies are not found in apple producing parts of China and, as the commenter observes, apple is not a primary host. Thus infestations of apple would be unusual and exclusionary mitigations like bagging will help prevent any infestation. We found references indicating the host status of apples (regardless of major or minor status) for the honeydew moth whereas we did not for either melon fly or solanum fruit fly. If, upon inspection, melon fly or solanum fruit fly are found to be generally infesting shipments of apples we will adjust our mitigations as necessary.

One commenter stated that there is an unknown risk of apple leaf miner escaping detection.

We disagree with the commenter's claim that apple leaf miner may easily escape detection. Leaf miners are not typically found on fruit; leaves, which they more readily infest, are not authorized for importation. In addition, leaf miners typically leave a visible tunnel as they mine, which aids in inspection and detection.

Another commenter asked why apple ring rot (Macrophoma kawatsukai) and the fungus, Penicillium diversum, were removed from the pest list when both were present on a draft version of the list. The commenter asked why the genus Penicillium is considered non-actionable at ports of entry.

These pests are post-harvest pathogens. In general, post-harvest pathogens are not considered for analysis because most are cosmopolitan and it is unlikely to impossible for them to be transferred to fruit in the field. Penicillium is a cosmopolitan genus that only causes post-harvest rots. Consequently, it is not actionable. APHIS determines whether a pest is actionable based on its novelty and known prevalence or distribution within and throughout the United States, its potential harm to U.S. agricultural, environmental, or other resources, and the need to mitigate its pest risk, if any.

The same commenter stated that spores from the fungal pathogens Monilia polystroma and Monilinia fructigena might easily go undetected in inspections and present a risk of becoming established on several crops in the State of Florida.

Phytosanitary security is provided by several layers of inspection: Field inspection, packinghouse inspection, and port of entry inspection. As these inspections take place over a period of time, it becomes increasingly likely that any consignments with symptomatic fruit will

be identified. As stated previously, these mitigations have been successfully used on a similar pest complex for the importation of pears from China.

The same commenter stated that, contrary to APHIS's assertion in the PRA that interception records indicate no association between Tetranychus species of spider mite and commercially produced and shipped apples, the apple industry has experienced infestations of Tetranychus and Panonychus spider mite species in apple production areas. The commenter added that the hawthorn spider mite (Amphitetranynchus viennensis) could present a similar risk given that it is recorded as attacking leaves, fruit, and blossoms. Another commenter stated that, late in the growing season, hawthorn spider mites sometimes collect in the calices of apples, with either motile forms or eggs present. The commenters urged APHIS to reexamine the data in light of this.

While we have made no changes in response to this comment, as the data we have do not support the commenters' assertion, we do note that typical required mitigations for spider mites are packinghouse procedures (i.e., washing, brushing, spraying with compressed air), culling, and inspection. Those measures will be included as requirements in the operational workplan and should mitigate against any unforeseen pests of this nature. If one of these pests is detected upon inspection we will take appropriate measures to prevent its introduction into the United States. The hawthorn spider mite was considered in the PRA. It attacks apple leaves; we found no evidence of it being present on fruit.

The same commenter asked why Eotetranychus sp. mites were listed as being associated with apples in China with actionable or undetermined regulatory status but was not included in the listing of actionable pests reported on apples in any country and present in China on any host.

While Eotetranychus sp. mites are generally actionable, investigation into the Eotetranychus species that are present in China and known to affect apples did not reveal any known species that are considered actionable in the United States, so we did not include them in the second listing. Some non-actionable species from this genus are listed in an appendix to the PRA.

The same commenter expressed concern that multivoltine fruit feeding insects may be able to oviposit on fruit once the bags that are required by the systems approach to be placed over each developing fruit are removed. The commenter further asked that APHIS ensure that the required fruit bags are not applied too late in the spring or removed too early as the fruit matures in the interest of addressing horticultural quality needs and color development at the expense of pest mitigation.

Our requirement, which will be stipulated in the operational workplan, is that the bags must remain on the fruit until at least 14 days before harvest. PPQ will ensure that the bags are in place early enough to exclude insect pests. If infestations of insects such bagging is intended to exclude are found upon inspection, production sites and packinghouses may be suspended from the export program.

The same commenter stated that snout beetles (Curculionidae) can be serious pests of tree fruit with limited control options. While the commenter noted that the PRA lists a number of Curculionidae species as following the importation pathway, the commenter noted the following additional species of weevils for inclusion: Coenorrhynus sp., Enaptorrhinus sinensis Waterhouse, Involvulus sp., Neomylloceris hedini (Marshall), Rhynchites coreanus Kono, and Rhynchites heros Roelofs.

In particular, the commenter asked why Enaptorrhinus sinensis Waterhouse is listed as infesting fruit, but unlikely to follow the pathway of importation. The commenter observed that Enaptorrhinus sinensis Waterhouse is one of three species on the PRA list of quarantine pests that are likely to follow the pathway that is classed as a fruit feeder. The commenter went on to state that Neomyllocerus hedini (Marshall) is also present on the PRA list of quarantine pests that are likely to follow the pathway.

Finally, the commenter stated that an Australian PRA cites Rhynchites coreanus Kono as a high-risk quarantine pest from China, but was not considered in the APHIS PRA.

The bagging requirement discussed above should effectively exclude Curculionidae. In addition, weevils typically leave feeding damage and holes with frass that are easily visible upon inspection. We would note that we analyzed Rhynchites heros Roelofs and determined that it presents a medium risk of introduction via the importation pathway and that Rhynchites coreanus Kono is a synonym of Rhynchites heros Roelofs.

Contrary to the commenter's assertion, Enaptorrhinus sinensis Waterhouse is not listed in the PRA as affecting fruit: "Adults, which are moderately large beetles (body length: 6.2-6.4 mm, width: 3.2-3.3 mm; Han, 2002), may feed on apple fruit (You, 2004), but are considered unlikely to remain with fruit through harvest and post-harvest processing." Neomyllocerus hedini (Marshall) is listed as affecting leaves but not fruit.

As for the other weevils cited by the commenter, we found no evidence during our assessment that those pests were likely to follow the pathway.

The same commenter observed that, since members of the Diaprididae and Pseudococcidae families of scale insects feed on stems, leaves, and fruit in U.S. apple orchards and are treated as quarantine pests in many countries around the world, the following species

should have been included in the PRA: Diaspidiotus (= Quadraspidiotus) slavonicus (Green), Phenacoccus pergandei Cockerell, Spilococcus (= Atrococcus) pacificus (Borchsenius), and Leucoptera malifoliella (Lyonetiidae).

Another commenter said that the PRA's determination of a negligible possibility of Japanese wax scale (Ceroplastes japonicas) following the pathway of importation was based on the idea that Chinese apples will be safely discarded. The commenter stated that, if even a small percentage of imported apples are discarded improperly, there is risk, particularly if they are discarded near host material.

In general, scale insects are excluded via washing, brushing, spraying with compressed air, culling, and inspection. These mandatory measures will be a part of the operational workplan. However, Phenacoccus pergandei Cockerell is found to affect leaves only, Spilococcus (= Atrococcus) pacificus (Borchsenius) is found to affect stems only, and Ceroplastes japonicas is found to affect both leaves and stems. The commenters provided no evidence that these scales were of concern on fruit. Although Leucoptera malifoliella (Lyonetiidae) is not on the pest list, Leucoptera malifoliella (Costa) is listed with a high risk of following the pathway and will be mitigated as described previously. Lyonetiidae is the family name for this pest, Costa is the authority. They are the same pest, notated differently. Finally, in a risk analysis titled, "Phytosanitary Risks Associated with Armored Scales in Commercial Shipments of Fruit for Consumption to the United States" (June 2007)⁶ we determined that the likelihood of introduction of armored scales via the specific pathway represented by commercially produced fruit shipped without leaves, stems, or contaminants is low because these scales have a very poor ability to disperse from fruits for consumption onto hosts. Females do

⁶ Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

not possess wings or legs; legs are also absent in feeding immature forms. Males are capable of flight, however they are short-lived, do not feed, and tend to mate only with nearby females. For this reason, the armored scale Diaspidiotus (= Quadraspidotus) slavonicus (Green) is not a pest of concern.

One commenter stated that since the taxonomy of the fungus Botryosphaeria dothidea is under active consideration by the research community, the assertion that the Asian Botryosphaeria dothidea is the same species as is found in the United States is not settled science. The commenter argued that they should be considered distinct species until scientists from China provide additional studies demonstrating that they are synonymous.

We disagree. The most recent and conclusive study on this matter⁷ found that the causal agent of apple ring spot and apple white rot was the same. The agent was identified as Botryosphaeria dothidea for both diseases. Thus, the pathogen is present in both the United States and China.

Another commenter stated that there is an unknown risk of fungi of the genus Monilinia escaping detection.

We disagree with the commenter's assertion regarding unknown risk. Monilinia mali is unlikely to be present on mature fruit. Monilinia fructigena is unlikely to come in contact with host material, since spores need to be near actual apple trees. Unless Monilinia fructigena-infected fruit are sporulating in close proximity to host material, they cannot infect it and we consider this possibility unlikely. Other specific members of Monilinia sp. are discussed below.

⁷ That study, Phylogenetic and pathogenic analyses show that the causal agent of apple ring rot in China is Botryosphaeria dothidea, may be found on the Internet at <http://apsjournals.apsnet.org/doi/pdf/10.1094/PDIS-08-11-0635>.

One commenter said that it needs to be demonstrated, through scientific study and examination of mature fruit taken from orchards which have suffered epidemics at several early seasonal timings, that latent infections of the fungus Monilinia ma/1, which is the causal agent of monilia leaf blight, are not sometimes still present later at harvest on normal appearing fruit.

Field inspection data for Monilinia fructigena and Monilinia polystroma was presented by all orchards inspected in our site visit and certified by the Chinese Entry and Exit Inspection and Quarantine Service. This data shows no report of the diseases, and if there are no disease records, then there can be no latency problem such as the commenter described. In addition, packinghouse inspections show no history of the disease.

The same commenter said that the fungus Monilinia mali, which does not occur in the United States, was not included in the listing of actionable pests reported on apples in any country and present in China on any host and should be added. The commenter additionally stated that the fungus Monilinia polystroma should be added to that list as well, as it has been reported to attack apples in Europe and has been recently reported from China.

Contrary to the commenter's assertion, both pathogens are listed. Currently there is only a single report of Monilinia polystroma on apples. That identification is debatable since it was based on molecular evidence alone. The European report stated that the symptoms disappeared after the initial observation. Thus, the observations have not been replicated outside of this single incident. In Japan and China, where stone fruit (the primary host for the pathogen) and apples are grown in close proximity, there are no reports of Monilinia polystroma on apples. Despite the weak evidence, we did analyze Monilinia polystroma and found it to be high risk. It was therefore considered when we were developing the requirements of the systems approach

and will be considered in development of the operational workplan. There is also considerable uncertainty about the presence of Monilinia mali but it was also listed. However, it was not analyzed because it is not found on mature fruit.

The PRA lists certain organisms that APHIS is only able to identify to the genus level and notes that these organisms may prove to have actionable status. One commenter noted this and categorized this as an arbitrary decision by APHIS. The commenter stated that APHIS is incorrect to say that the risk potential of these species should be considered low because APHIS cannot evaluate risk as completely as would be desirable. The commenter appears to suggest that APHIS study these unknown organisms further or that APHIS evaluate risk for genera taken as a whole.

Another commenter requested further information regarding the following fungi, identified only to the genus level, which were listed as being associated with apples in China with actionable or undetermined regulatory status: Cladosporium, Fusarium, Fusidium, Penicillium, and Psuedocercospora. The commenter stated that these may represent novel species and wanted to know if APHIS went back to original sources or voucher specimens to attempt to confirm the specific identity of these fungi.

Another commenter observed that some pest organisms were only identified to the genus level in the PRA and are thus not included in the evaluation. The commenter particularly cited Drosophila sp. as of potential concern, stating that, though many members of the species only attack and reproduce in damaged fruit, the U.S. apple industry has found that the spotted-wing drosophila (Drosophila suzukii) readily attacks and reproduces in intact fruit. The commenter

said that this behavior is present in many plant-attacking arthropods and added that the Chinese arthropod fauna is very poorly known and therefore we have no idea of their geographic or host ranges and, consequently, their possible agricultural and ecological impacts.

These commenters ask APHIS to meet an impossible standard of certainty in terms of species knowledge. Further, the SPS Agreement allows for signatory countries to only consider risks that are known and scientifically documented. Under the SPS Agreement, if a country cannot scientifically document the risk associated with a given pest or commodity as a whole, then that country cannot mitigate that unknown risk by imposing phytosanitary requirements or denying market access. We do not have access to any further information on the specific species cited by the commenters as there is no existing research on these species beyond the genus level. While, as stated, we are unable to assess the risk associated with scientifically unknown species, we include the genera in the PRA in case more information is discovered later. In the event of new pest information and research, we will adjust our mitigations as necessary.

Another commenter stated that the sooty blotch and flyspeck complex of fungi, which occurs in China, represents a phytosanitary challenge given that most of these fungi have an extremely long incubation period or latent period before colonies become visible on fruit surfaces. Additionally, the commenter identified three species, Zygophiala cylindrical, Zygophiala qianensis, and Strelitziana mali, which are reported to occur on apples in China but are not included on the pest list.

As with Penicillium, which was discussed previously, these pests are post-harvest pathogens. In general, post-harvest pathogens are not considered for analysis because most are cosmopolitan and it is unlikely to impossible for them to be transferred to fruit in the field.

The same commenter observed that nematodes are often mistakenly considered to be solely root feeders. While root feeders would not likely be expected to be part of the fruit pathway, Aphelenchoides limberi, a shoot feeder, might present a higher risk than assigned in the pest list and therefore be deserving of additional consideration. The commenter asked why no Ditylenchus or Anguina species were included in the PRA, given the regional proximity of seed-gall nematode, Anguina tritici.

As the commenter stated, generally speaking, nematodes inhabit the soil and infest plant roots. While there are a few tissue feeding species, it is highly unlikely that any will be present on apples given that they are shoot feeders and not pathogens of the mature fruit. We are confident that the PRA has captured all fruit feeding pests of concern.

The same commenter observed that the moth Spulerina astaurota, the lace bug (Stephanitis (Stephanitis) nashi Esaki & Takeya, 1931), and the tortricid moths Acleris fimbriana, Adoxophyes orana, and Spilonota lechriaspis are listed as associated with fruit in a 2003 Australian review of pests associated with Chinese pears. The commenter said that this association should prove true for apples from China as well and these pests should therefore be added to the pest list.

We are aware of the review referenced by the commenter but disagree with the commenter's conclusions. Our examination of the source literature for the review as well as other documents did not indicate that any of these pests, with the exception of Adoxophyes orana, is present on apple fruit. Adoxophyes orana was analyzed in the PRA and we determined that it presents a medium likelihood of introduction. It is therefore covered by the mitigations in the systems approach.

Another commenter asked why the summer fruit tortrix (Adoxophyes orana) and the plum fruit moth (Cydia funebrana) would not require an approved treatment in regions where these pests are present, as will be required for Oriental fruit fly.

These pests are mitigated by the required bagging protocol that is part of the systems approach. Bagging excludes all Lepidoptera pests. This systems approach has been used for pears from China for the past 15 years, resulting in a very low number of Lepidoptera sp. interceptions.

Another commenter stated that, although there are four species of thrips (Thysanoptera) listed in the PRA, none were considered to follow the pathway of importation since they only damage leaves. The commenter said that many thrips are known to shelter in the calyxes of fruit and could enter the importation pathway in this manner.

We disagree with the commenter's assessment. Apart from principally attacking leaves, thrips are a highly mobile pest. Any thrips that sheltered in the fruit calyx or elsewhere would not do so for long and would be mitigated by the required washing, brushing, and spraying with compressed air at the packinghouse.

The same commenter said that the PRA did not consider the pear fruit borer (Pempelia heringii) as a candidate for risk management based primarily on the fact that it has not been a significant pest in the last 100 years, but that records indicate that it was a pest that bored into the fruit of apples and pears. The commenter stated that a report of this species in Hawaii throws into doubt the restricted host range it is thought to have and therefore the precautionary principle should be applied in including it on the pest list.

One of the risk elements analyzed in the guidelines for risk assessment is damage potential in the endangered area. Considering all available information, the analysis determines whether or not a significant level of damage would be likely to occur in the endangered area (e.g., more than 10 percent yield loss, significant increases in production costs, impacts on threatened or endangered species). As the commenter notes, reports of significant damage in fruit production as a result of Pempelia heringii infestation are over 100 years old. Apple and pear production in China and Japan are economically important aspects of national agriculture; if significant damage was to occur again, it would have been reported in the literature. While there is some uncertainty regarding the cause of the absence of Pempelia heringii infestations, based on available literature, the potential for damage in the United States is considered low.

The same commenter stated that the mealybug Pseudococcus cryptus was not considered a candidate for risk management in the PRA because risk of establishment was considered first, and since that was deemed negligible, the likelihood of introduction was not evaluated. The commenter said the argument regarding negligible establishment is based on the idea that it is unlikely that an infested fruit will be discarded near a potential host, as well as the presumed frailty of the crawlers. The commenter went on to say that, in the event that apples are or become a host, the crawlers of other mealybug species are known to aggregate around the calyx of fruit, which would provide shelter and render them difficult to detect and therefore the absence of any mealybug species from the PRA list for risk management measures should be examined.

The mealybug analysis concludes as follows: “Dispersal by wind is dependent on prevailing wind direction; nymphs have no control over where they are blown. This dispersal strategy relies on a very high number of nymphs, so that a few will arrive serendipitously on a

suitable new host. Commercial fruit arriving in the United States is highly unlikely to carry high populations of pregnant females. Crawlers would be unlikely to survive shipment, especially in chilled, low humidity conditions. Some people dispose of inedible fruit in outdoor compost bins, but since only a small number of fruit are likely to be infested, only very rarely would infested fruit be composted. For these reasons, mealybugs arriving on commercial fruit for consumption have a negligible likelihood of dispersing to hosts.” Sufficient evidence to change this has not been presented.

The same commenter observed that the oriental red mite (Eutetranychus orientalis) was dismissed as a risk by the PRA as there were no records indicated in a “thorough National Agricultural Library, Google Scholar, and PestID database search.” The commenter stated that, to the contrary, there is literature that lists Eutetranychus orientalis as a pest of apple and other rosaceous hosts.

This species is a well-known and thoroughly researched pest of citrus. Given the vast amount of literature available on this species, primary records of detections on apple should be available, if extant. Given the lack of such primary records, we consider the listing of apples as a natural host for Eutetranychus orientalis dubious and therefore we did not include it on the pest list.

The same commenter stated that the peach fruit moth (Carposina sasakii) is treated as not meeting the criteria for spread potential in the PRA, but that the PRA also states that the lack of spread is due to strict quarantine regulations. The commenter went on to say that this is a serious pest in infested regions and should be included for risk management.

We concluded in the PRA that the peach fruit moth was likely to cause unacceptable consequences if introduced into the United States. It was assigned a medium likelihood of introduction and is therefore covered by the requirements in the systems approach.

Comments on the Systems Approach

We proposed to require the NPPO of China to provide an operational workplan to APHIS that details the activities that the NPPO would, subject to APHIS' approval of the workplan, carry out to meet the requirements of the regulations. An operational workplan is an agreement between PPQ, officials of the NPPO of a foreign government, and, when necessary, foreign commercial entities that specifies in detail the phytosanitary measures that will comply with our regulations governing the import or export of a specific commodity. Operational workplans establish detailed procedures and guidance for the day-to-day operations of specific import/export programs. Workplans also establish how specific phytosanitary issues are dealt with in the exporting country and make clear who is responsible for dealing with those issues. The implementation of a systems approach typically requires an operational workplan to be developed. Two commenters stated that since the operational workplan, in particular the section on required production practices, has not yet been approved by APHIS it was impossible to adequately evaluate the risks of the proposal. Another commenter asked us to present details of the operational workplan.

Generally speaking, APHIS does not finalize an operational workplan until after the rule itself is finalized given that changes may be made to the rule as a result of public comment. However, given the similarity of the systems approaches, we anticipate that the operational workplan associated with the importation of apples from China will be very similar to the

workplan for the importation of pears from China, which has been used to mitigate risk successfully for the past 15 years. This will likely include such requirements as field inspection, orchard control, culling, and spraying with compressed air.

We proposed to require that, when any apples destined for export to the continental United States are still on the tree and are no more than 2 centimeters in diameter, double-layered paper bags must be placed wholly over the apples.

We are making a minor change to the requirements as they pertain to when the bags are placed as they were set out in the proposed rule. Instead of requiring that bags be placed over the apples when they are no more than 2 centimeters in diameter, we are requiring that the bags be placed over the apples when they are no more than 2.5 centimeters in diameter. The 2 centimeter diameter specified in the proposed rule was an error and the change to 2.5 centimeters is necessary to keep the regulations in line with bagging protocols for pears from China. The change from 2 centimeters to 2.5 centimeters will have no effect on the phytosanitary safety of the young apple fruit. At this stage in the fruit's growth any attacks made by surface feeding or internally feeding pests will lead to visible deformation of the fruit and to fruit drop. Further, an increase of 0.5 centimeters in fruit diameter at this stage represents generally a week's worth of growth, which is insufficient time for any widespread infestation of young fruit to occur.

Two commenters asked which studies confirm APHIS's assertion that bagging the fruit will mitigate all the pests of concern discussed in the PRA. Another commenter wanted to know whether APHIS can prove the effectiveness of fruit bagging as a phytosanitary mitigation based on the volume of apples that will likely be shipped. Another commenter pointed out that we had modeled the bagging protocol on a similar protocol for the importation of pears from China, and

that pears imported under this protocol had sometimes been determined to be infested with plant pests. The commenter stated that this calls into question the efficacy of this mitigation.

We did not claim that the required bagging will serve as sole mitigation for the pests of concern listed in the PRA. The entire systems approach, which comprises a number of requirements working in concert, will provide that mitigation. While we do not possess evidence regarding the efficacy of bagging for apples in particular, the efficacy of bagging as a means of preventing fruit from becoming infested with quarantine insects is well established: The RMD cited several peer-reviewed studies regarding its efficacy. Additionally, we note that bagging is a pest-exclusionary technique that is similar to safeguarding with mesh, tarps, containment structures, and other mitigations APHIS has relied on to prevent pests from following the pathway of fruits for many years.

Fruit bagging has been a required aspect of the systems approach for the importation of pears from China for the past 15 years. This program experiences an extremely low interception rate—15 interceptions in 15 years—with an import volume of about 10,000 MT annually. Although it is not possible to say with absolute certainty, given the structure and past behavior of the Chinese apple industry, which is discussed in detail in the final regulatory flexibility analysis, we expect apples to be imported at a similar rate. Contrary to the third commenter’s claim that 15 pest interceptions over a 15 year period is troubling, given the time period in question and the level of imports during that time, this interception rate does not call into question the efficacy of bagging, but rather underscores its efficacy.

We proposed to require the NPPO of China to visit and inspect registered places of production prior to harvest for signs of infestations. One commenter stated that the required interval for inspection was insufficient and would not serve to ensure compliance. Two

commenters said that the required inspection frequency was also inadequate to enforce the requirement for removal of fallen fruit at the place of production.

As stated in the proposed rule, this provision is modeled on an existing provision that has been successfully employed as part of the systems approach that used by APHIS for the importation of fragrant pears and sand pears from China. Given our knowledge and experience with the importation of these pears, we are confident that the requirement is adequate. In addition, as with any regulatory program, unannounced inspections and spot checks are often used to ensure compliance. Suspension or expulsion from the export program would also serve to discourage noncompliance. Our approach to any required orchard procedures, such as the removal of fallen fruit, would be the same.

We proposed to set forth requirements for mitigation measures that would have to take place at registered packinghouses. These measures include a requirement that during the time registered packinghouses are in use for packing apples for export to the continental United States, the packinghouses may only accept apples that are from registered places of production and that are produced in accordance with the regulations, tracking and traceback capabilities, establishment of a handling procedure (e.g., culling damaged apples, removing leaves from the apples, wiping the apples with a clean cloth, air blasting, or grading) for the apples that is mutually agreed upon by APHIS and the NPPO of China, washing, brushing, spraying with compressed air, and box marking. A commenter said that the inspection procedures for packinghouses do not provide sufficient detail. The commenter said that packinghouse inspections must adequately ensure that leaf removal and washing of apples are conducted according to applicable requirements and added that the packinghouse must address the risk associated with apples originating from nonregistered places of production that may have been

processed ahead of the packaging of the apples destined for U.S. markets. Several commenters stated that we should require that Chinese packinghouses handling apples intended for export to the United States not accept commodities destined for any other markets given that the phytosanitary standards required to access non-U.S. markets may be weaker. Another commenter pointed out that the size of the required biometric sample was unspecified. Another commenter stated that packinghouse culling and inspection do not eliminate all lepidopteran and curculionid pests in the United States, so APHIS should not assume that they will do so in China.

As stated previously, APHIS inspectors have the authority to reject consignments that contain contaminants such as leaves and other plant debris, especially if any pests are found to be generally infesting that shipment. As stipulated in § 319.56-3(a), “All fruits and vegetables imported under this subpart, whether in commercial or noncommercial consignments, must be free from plant litter or debris and free of any portions of plants that are specifically prohibited in the regulations in this subpart.” Washing of apples will be required under the regulations, with specific washing procedures set out in the operational workplan. We will also stipulate that packinghouses may not be used for packing apples from non-registered places of production simultaneous to packing apples from registered places of production. Requiring a facility be dedicated for shipping only to the United States is not technically justified if that facility can demonstrate and practice effective methods for identifying and segregating fruit destined for different markets.

The specifics of packinghouse inspection procedures are listed in the operational workplan in order to offer the greatest amount of flexibility in responding to any rapidly changing pest issues that may arise. Typically APHIS will require at least 300 fruit be inspected, a number that will detect a 1 percent or greater pest population with 95 percent confidence.

APHIS will also require that a portion of the fruit be cut open to look for internally feeding pests. Any fruit with damage or signs of pest presence will be sampled first.

We disagree with the commenter's assessment of the presence of lepidopteran and curculionid pests in the United States post culling and inspection. The commenter did not provide any support for the claim that these pests are evading domestic phytosanitary measures.

One commenter said that, while box labeling and traceback information are vital to prevent the further spread of any plant pest, this information alone does not prevent the establishment of the pest in the United States.

We agree. However, box labeling and traceback are only one aspect of the required systems approach for the importation of apples from China. The systems approach must be considered as a whole with its combined effect of various mitigation measures in order that its pest mitigation capabilities be fully assessed. We are confident that it will prove effective.

We proposed to require treatment of fumigation plus refrigeration for those apples grown south of the 33rd parallel, since Oriental fruit fly is known to exist, in varying population densities, in that region. One commenter stated that it is possible that a mutated gene may eventually allow a number of Oriental fruit flies to resist fumigation.

If Oriental fruit flies were to become resistant to the designated phytosanitary treatment, the import program would be shut down completely until an investigation has been completed and the reason for the program failure resolved.

Several commenters stated that we should require that Chinese cold storage facilities housing apples intended for export to the United States not accept commodities destined for any other markets given that the phytosanitary standards required to access non-U.S. markets may be weaker.

Requiring a facility be dedicated for shipping only to the United States is not technically justified if that facility can demonstrate and practice effective methods for identifying and segregating fruit destined for different markets.

Comments on the Economic Analysis

We prepared an initial regulatory flexibility analysis in connection with the proposed rule regarding the economic effects of the rule on small entities. We invited comments on any potential economic effects and received a number of comments. Those comments are discussed and responded to in detail in the final regulatory flexibility analysis associated with this final rule. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Comments on General Economic Effects

While specific comments on the initial regulatory flexibility analysis are addressed in the final regulatory flexibility analysis as previously stated, we received a number of comments concerning the overall economic effect of the rule as it relates to U.S. trade policies concerning China that are more appropriately addressed here.

One commenter stated that APHIS did not meet those requirements of Executive Order 13563 that specify that agencies must take into account the benefits and costs, both qualitative and quantitative, of the rules they promulgate. The commenter specifically said that APHIS had failed to demonstrate that the proposed rule provided any benefit to U.S. consumers and stakeholders.

We disagree with the commenter's assessment. Executive Order 13563 requires that agencies propose or adopt a regulation upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify). The Executive Order also states that, where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. The Executive Order ultimately leaves the type of analysis to the discretion of the Agency. We have previously explained the reasons for which APHIS conducts qualitative rather than quantitative analyses.

As detailed in the initial regulatory flexibility analysis that accompanied the proposed rule and restated in the final regulatory flexibility analysis associated with this rule, we find it unlikely that the importation of apples from China will represent a cost to the U.S. apple industry or to U.S. consumers. This is due to the relatively small amount of apples that are expected to be exported and qualitative factors associated with consumer demand such as variety, flavor (acids, sugars, aroma), juiciness, crispness, firmness, appearance (color, shape and size), freshness, perceived health benefits, production method (organic or conventional), and product origin (local, regional, domestic or import). Moreover, trade with China represents an opportunity for potential expansion of the U.S. export market and the benefits associated with such an expansion.

One commenter claimed that China is not an open market for fair trade and, as a result, efforts to market U.S. apples in China in return for allowing Chinese apples access to U.S. markets will prove unsuccessful. Another commenter said that, in the past, China claimed that

U.S. apples presented unacceptable phytosanitary risk and subsequently halted all importation of apples from the United States into China. The commenter stated that this was done without substantiated claims or investigation as a tactic to force the United States to open its markets to Chinese apples.

We disagree with the claim that China's prohibition on the importation of apples from the United States was without basis and was motivated by bilateral trade concerns. In 2012, the NPPO of China suspended access for red and golden delicious apples from the State of Washington due to repeated interceptions of three apple pests the NPPO considers significant: Speck rot (caused by Phacidiopycnis washingtonensis), bull's-eye rot (caused by four species of Neofabraea), and Sphaeropsis rot (caused by Sphaeropsis pyriputrescens). In response, APHIS worked with the U.S. apple industry to develop additional safeguarding measures to address China's concerns about these pests. As a result, red and golden delicious apples were permitted to be imported from the United States into China beginning in early November 2014.

Another commenter stated that Chinese import competition affects local labor markets by triggering declines in associated wages and employment.

While APHIS is sensitive to the costs its actions may impose on producers in the United States, as detailed in the final regulatory flexibility analysis, apples are not inexpensive to produce in China due, in large part, to differences between the way the apple industry is structured in the United States and China. Most apple growers in China operate on a very small scale and production is labor-intensive, requiring significant labor resources to plant, tend, and harvest the crop.

One commenter urged APHIS to support and encourage consumers in doing business with local farmers. The commenter claimed that the low price of Chinese apples would cause domestic producers economic distress.

We would observe that consumer practices when purchasing fresh apples are influenced by factors other than price. These factors include variety, size, color, flavor, texture, freshness, product origin, and production method. American consumers benefit from a diverse and abundant supply of fresh apples that are locally, regionally, and nationally distributed to them; it is highly unlikely that China will become a dominant supplier.

Comments on Bilateral Trade

Several commenters pointed out that access to Chinese markets for U.S. apples is not currently assured at this point in time. The commenters asked that APHIS make sure that the proposed rule would not be finalized before reciprocal market access is granted. One of the commenters added that, if Chinese apples were able to be imported into the United States, but U.S. apples could not be exported to China, then the underlying assumptions concerning the economic impact of the importation of apples from China would prove incorrect. Another commenter stated that, if China were to allow for the importation of apples from the United States, there is concern that small American producers will not be able to make such market access opportunities profitable. Another commenter suggested that APHIS regulate the amount and variety of apples allowed into the United States from China.

Other countries make decisions as to whether to allow the importation of U.S. products only when formally requested. APHIS formally requested that China allow the importation of U.S. apples, and we worked with the U.S. apple industry to address concerns raised by the NPPO of China, resulting in the successful reopening of the Chinese apple market to U.S. apple growers

in November 2014. However, APHIS' primary responsibility with regard to international import trade is now, and has been for many years, to identify and manage the phytosanitary risks associated with importing commodities. When we determine that the risk associated with the importation of a commodity can be successfully mitigated, it is our responsibility under the trade agreements to which we are signatory to make provisions for the importation of that commodity. Moreover, under the PPA, our decisionmaking related to allowing or denying the importation of commodities must be based on phytosanitary considerations rather than the goal of reciprocal market access.

Another commenter stated that the PPA requires that APHIS base its regulations on sound science and that the desire for reciprocal apple trade with China is not science-based. The commenter said that if hope of such mutual access was influential in the development of the proposed rule, then the rule is not compliant with the PPA, and therefore illegal. The same commenter also stated that such a situation violates the conditions of the SPS Agreement, particularly Article 2.2, which requires that signatories base sanitary and phytosanitary regulations on scientific principles, and Article 5.1, which requires that signatories base their actions on a risk assessment. The commenter reiterates that reciprocal trade is neither a scientific principle nor a risk assessment and APHIS's proposed action may therefore be out of compliance with the SPS Agreement.

This action was predicated on several risk assessment documents that provide a scientific basis for potential importation of apples from China. Without these risk assessment documents, which have withstood several reviews and public comment periods, APHIS would not have proposed this action. Political and economic interests may stimulate consideration of the expansion of trade of agricultural commodities between countries, but all decisionmaking

concerning phytosanitary restrictions on trade must be science-based. APHIS stands behind the risk assessment documents that support this rule, and believes they are based on sound science.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Apples are the second most popular fresh fruit for U.S. consumers and the third most valuable fruit crop produced in the United States. The United States is the world's second largest apple producer and became the world's largest apple exporter in terms of value in 2012, generating a surplus of \$909 million in fresh apple trade (exports minus imports). That year, the United States commercially produced 4.1 million metric tons (MT) of apples, valued at \$3 billion, of which 3 million MT of apples were sold fresh and 1.1 million MT were used for processing. Although apples are commercially grown in all 50 States, 9 States accounted for 96 percent of production. The State of Washington was by far the largest producer, at more than 2.9 million MT per year (over 70 percent of the U.S. total).

Almost all apple farms are family-owned, and many of these families have been engaged in apple production for many generations. The U.S. apple industry is challenged by relatively

flat domestic apple consumption, and its continued growth relies on expanded global trade. Roughly 30 percent of fresh apples produced in the United States were exported in 2012. That year, roughly 8 percent of fresh apples consumed in the United States were imported, totaling 183,000 MT and valued at \$164 million. Virtually all imports came from four trading partners: Chile, New Zealand, Canada, and Argentina.

By quantity, China was the world's largest producer, consumer and exporter of apples in 2012. (In 2013, Poland became the world's largest exporter of apples in quantity, whereas the United States remained the world's largest exporter of apples in value). Apples are the leading fruit produced in China, with production having increased from 2.3 million MT in 1978, to 38.5 million MT (33.3 million MT for fresh markets and 5.2 million MT for processing) in 2012. China's apple consumption has grown to 37.5 million MT.

In contrast to that of the United States, China's apple industry relies marginally on international trade – in 2012, it exported about 3 percent of fresh apples produced and imported 0.1 percent of fresh apples consumed. China's exports of fresh apples peaked in 2009 at 1.2 million MT and declined to 0.98 million MT in 2012. Most of the 4.3 million apple growers in China operate on a small scale, with farm acreages averaging 1.3 acres. The Fuji variety accounts for about 70 percent of China's apple production. China's heavy dependence on the Fuji variety is in sharp contrast to the many diverse varieties produced in the United States. China's export markets are concentrated in Russia, Southeast Asia, and the Middle East. Chinese fresh apples also have been exported for more than a decade to Canada; however, Canada accounted only for 0.4 percent of China's fresh apple exports in 2012. In fact, China's combined export volume to Canada, European Union (EU) member countries, Australia, and Mexico is very small (0.8 percent of its total fresh apple exports in 2012), and has significantly

declined in the last 6 years, from 45,267 MT in 2007 (4.4 percent of Chinese apple exports) to 8,273 MT in 2012. Average export prices of fresh apples from China in 2012 to the aforementioned countries (Canada, \$1.50/kilogram (kg); EU, \$1.10/kg; Australia, \$1.83/kg; and Mexico, \$1.55/kg) are consistently higher than the average price paid in all 67 countries to which China exported fresh apples (\$0.98/kg). It is reasonable to expect that price for fresh apples exported to the United States will be similar to prices paid in Canada and Mexico. Considering the current availability of relatively low-priced imported apples in the United States and the wide range of domestic varieties, apples imported from China are not likely to compete solely on price in the U.S. market. U.S. consumers make their purchasing decisions for fresh apples based not only on price, but also on intrinsic product attributes such as variety, color, size, flavor, texture, freshness, production method, and product origin.

Based on historic data of China's apple production, consumption, export volumes, and prices, we expect no more than 10,000 MT of fresh apples will be imported from China into the continental United States annually, which represents less than 0.44 percent of the U.S. domestic fresh apple supply and less than 5 percent of U.S. imports in 2012. Most of China's fresh apple exports to the United States will likely be shipped to West Coast ports, primarily ones in California, and are expected to be distributed through Asian ethnic supermarkets mainly to Asian communities.

California is the largest market for Washington State apples; any effects of the rule may be borne mainly by Washington and California apple growers. In particular, U.S. apple growers of the Fuji variety, which comprised about 8 percent of U.S. production in 2011, may be more directly affected by an increase in supply because we expect the majority of fresh apples from

China will be of the Fuji variety. However, given the relatively small quantity expected to be imported from China, any negative impacts for U.S. small entities will not be significant.

Executive Order 12988

This final rule allows apples to be imported into the continental United States from China. State and local laws and regulations regarding apples imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0423, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the Federal Register providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. Section 319.56–72 is added to read as follows:

§ 319.56–72 Apples from China.

Fresh apples (Malus pumila) from China may be imported into the continental United States from China only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: Adoxophyes orana (Fischer von Röslerstamm), summer fruit tortrix; Archips micaceana (Walker), a moth; Argyrotaenia ljugiana (Thunberg), grape tortrix; Bactrocera dorsalis (Hendel), Oriental fruit fly; Carposina sasakii Matsumura, peach fruit moth; Cenopalpus pulcher (Canestrini & Fanzago), flat

scarlet mite; Cryptoblabes gnidiella (Millière), honeydew moth; Cydia funebrana (Treitschke), plum fruit moth; Euzophera bigella (Zeller), quince moth; Euzophera pyriella Yang, a moth; Grapholita inopinata Heinrich, Manchurian fruit moth; Leucoptera malifoliella (Costa), apple leaf miner; Monilia polystroma van Leeuwen, Asian brown rot; Monilinia fructigena Honey, brown fruit rot; Rhynchites auratus (Scopoli), apricot weevil; Rhynchites bacchus (L.), peach weevil; Rhynchites giganteus Krynický, a weevil; Rhynchites heros Roelofs, a weevil; Spilonota albicana (Motschulsky), white fruit moth; Spilonota prognathana Snellen, a moth; and Ulodermis trigrapha Meyrick, a moth. The conditions for importation of all fresh apples from China are found in paragraphs (a) through (e) of this section; additional conditions for apples imported from areas of China south of the 33rd parallel are found in paragraph (f) of this section.

(a) General requirements. (1) The national plant protection organization (NPPO) of China must provide an operational workplan to APHIS that details the activities that the NPPO of China will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section.

(2) The apples must be grown at places of production that are registered with the NPPO of China.

(3) Apples from China may be imported in commercial consignments only.

(b) Place of production requirements. (1) The place of production must carry out any phytosanitary measures specified for the place of production under the operational workplan as described in the regulations.

(2) When any apples destined for export to the continental United States are still on the tree and are no more than 2.5 centimeters in diameter, double-layered paper bags must be placed

wholly over the apples. The bags must remain intact and on the apples until at least 14 days prior to harvest.

(3) The NPPO of China must visit and inspect registered places of production prior to harvest for signs of infestation and/or infection.

(4) If Monilia polystroma van Leeuwen or Monilinia fructigena is detected at a registered place of production, APHIS may reject the consignment or prohibit the importation into the continental United States of apples from the place of production for the remainder of the season. The exportation to the continental United States of apples from the place of production may resume in the next growing season if an investigation is conducted by the NPPO, and APHIS and the NPPO conclude that appropriate remedial action has been taken.

(c) Packinghouse requirements. (1) Packinghouses must be registered with the NPPO of China, and during the time registered packinghouses are in use for packing apples for export to the continental United States, the packinghouses may only accept apples that are from registered places of production and that are produced in accordance with the requirements of this section.

(2) Packinghouses must have a tracking system in place to readily identify all apples destined for export to the continental United States that enter the packinghouse and be able to trace the apples back to their place of production.

(3) Following the packinghouse inspection, the packinghouse must follow a handling procedure for the apples that is mutually agreed upon by APHIS and the NPPO of China.

(4) The apples must be washed and brushed as well as waxed or sprayed with compressed air prior to shipment.

(5) The apples must be packed in cartons that are labeled with the identity of the place of production and the packinghouse.

(d) Shipping requirements. Sealed containers of apples destined for export to the continental United States must be held in a cold storage facility while awaiting export.

(e) Phytosanitary certificate. Each consignment of apples imported from China into the continental United States must be accompanied by a phytosanitary certificate issued by the NPPO of China with an additional declaration stating that the requirements of this section have been met and the consignment has been inspected by the NPPO and found free of quarantine pests.

(f) Additional conditions for apples from areas of China south of the 33rd parallel. In addition to the conditions in paragraphs (a) through (e) of this section, apples from areas of China south of the 33rd parallel apples must be treated in accordance with 7 CFR part 305.
(Approved by the Office of Management and Budget under control number 0579-0423)

Done in Washington, DC, this 20th day of April 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015-09508 Filed: 4/22/2015 08:45 am; Publication Date: 4/23/2015]